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SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: PROLENE* (Polypropylene) 3D Patch

PREDICATE DEVICE NAME: PROLENE* (Polypropylene) Hernia System and Bard Marlex PerFix Plug

510(k) SUMMARY

Device Description

The PROLENE 3D Patch is a sterile three-dimensional device. The device is fabricated from PROLENE* Polypropylene Mesh. It consists of a flat mesh onlay patch secured to a formed expandable diamond shaped mesh patch component. The expandable patch portion of the device is a hollow diamond shaped component that is deployed through the use of an integrated looped non-absorbable suture.

Intended Use

The PROLENE 3D Patch is intended to be used for the repair of inguinal (direct and indirect) and abdominal wall hernia defects.

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510(k) SUMMARY, Continued

Indications Statement	The PROLENE 3D Patch is indicated for the repair of inguinal (direct and indirect) and abdominal wall hernia defects.
Technological Characteristics	The PROLENE 3D Patch has identical technological characteristics as compared to the predicate devices in that they are constructed of knitted polypropylene filaments. All the devices are pre-formed three dimensional devices with a top onlay patch that are to be secured in place with sutures.
Performance Data	Nonclinical laboratory testing was performed and concluded that the performance of the PROLENE 3D Patch for the repair of inguinal ring and abdominal wall defects was satisfactory and equivalent to the Bard Marlex Mesh PerFix Plug.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	Gregory R. Jones Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	March 8, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876

Re: K010722
Trade/Device Name: PROLENE (Polypropylene) 3D Patch
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: March 8, 2001
Received: March 12, 2001

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K010722

Device Name: PROLENE* (Polypropylene) 3D Patch

Indications for Use: The PROLENE (Polypropylene) 3D Patch is indicated for the repair of inguinal (direct and indirect) and abdominal wall hernia defects.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010722

(Optional Format 1-2-9G)